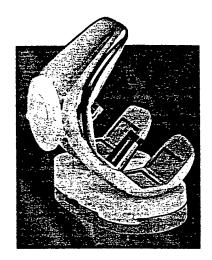
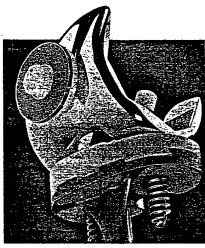
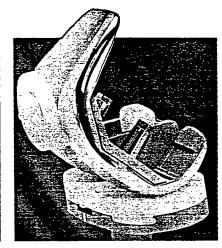
GENESIS®







PRIMARY SURGICAL TECHNIQUE

ANTERIOR REFERENCING INSTRUMENTATION



GENESIS Total Knee System and Instruments designed in conjunction with

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Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

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I INTRODUCTION

otal Knee Arthroplasty has undergone considerable evolution since the early prosthetic knee replacements. Yet despite improvements in the design of prosthetic replacements and surgical techniques, some clinical problems remain. Therefore, the challenge to both the surgeon and engineer is to define an implant system which can provide solutions to these clinical problems.

Many patients have ligamentous insufficiency, usually the posterior cruciate ligament and/or the collateral ligaments. Usually patients indicated for a total knee replacement have a deficient anterior cruciate ligament. Historically, various methods have been employed to address the instability of the knee joint, including prostheses with greater constraint between the articulating surfaces of the femur and tibia and hinged prostheses. The negative aspect of these methods, however, is that the inventory burden can become excessive. A solution is provided by using a prosthesis with modular articular inserts for the tibial components. Modularity allows a variety of articular surface types without the inventory burden associated with non-modular, "fixed" prostheses.

The need for modularity extends beyond the tibial component. Frequently, intraoperative decisions must be made regarding component dimensions, soft tissue balance, or ligamentous stability warranting changes in the choice of femoral component. Non-modular systems require a separate prosthesis, often requiring different bone cuts and different instruments. To address the problem more efficiently, a prosthetic knee system should feature components that can be modified through the addition of "conversion modules" to optimize surgical flexibility. The change from a Cruciate-Retaining to a Posterior-Stabilized component can be made intraoperatively by the addition of a conversion module to the standard femoral component.

Alignment is critical to the outcome of a total knee replacement. Instrumentation for total knees has evolved over time. To ensure that proper limb alignment is restored, a combination of intramedullary alignment devices with extramedullary alignment check rods is necessary. These steps increase the probability for a successful clinical outcome.

The management of bone defects can be a difficult problem in total knee replacement. A variety of methods can be employed including: filling the defects with cement, which can be reinforced with wire mesh or bone screws; altering the level of bone resection to eliminate the defect; the use of metal wedges or custom components; and the use of bone grafts.

Metal wedges provide more surgical flexibility than custom implants and can avoid some of the problems associated with other options for management of bone defects such as cement shrinkage or laminations, limited donor bone, or failure of graft incorporation. Metal wedge studies have shown that the levels of force transmission are uniform and approach that of a custom implant.

Preoperative planning provides only a limited view of the exact patient conditions for a total knee arthroplasty candidate. In some extreme conditions, the indications at arthrotomy reveal a different picture and require a different treatment. In order to best address this occurrence, a total knee system should be flexible enough to address the unexpected. The GENESIS Total Knee System is designed to do precisely that. The system incorporates features designed with clinically verified principles in mind. The modularity of GENESIS allows the surgeon to custom-assemble an implant for each individual patient.

The surgical technique that follows has been developed as a guide to using the GENESIS Anterior Referencing Instrumentation. It will demonstrate the primary and posterior-stabilized procedures. For both of these procedures, the GENESIS design combines superior fit with substantial flexibility.

DESIGN FEATURES

Raised lateral flange reduces chance of patellar subluxation.

Axisymmetric patellar articular surface eases surgical implantation.

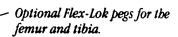
Asymmetric tibial tray sbape is more anatomically correct for maximum proximal tibial coverage.

Finned central stem evenly distributes stress and resists rotational forces.

Femoral component is a cobaltcbromium alloy for increased bardness and superior resistance to micro-fretting against polyetbylene when compared to titanium alloy.

Taller posterior condyles improve R.O.M. in bigber angles of flexion.

Distal and posterior condyles are both 7.5 mm "tbin" to minimize resection and maintain flexion/extension gap equivalence.



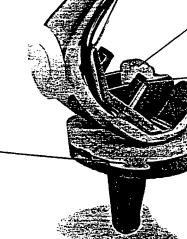
9.5 mm compression screws provide superior tibial fixation.

Hour-glass shaped cam maximizes contact area with the tibial eminence to minimize wear and

cold flow.

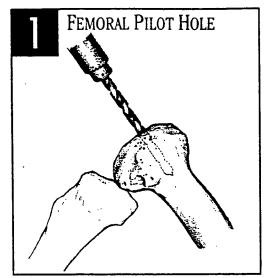
Conversion modules lock onto threaded posts with removable fixation lugs that eliminate relative motion and allow easy intraoperative conversion from a cruciate-retaining to a posteriorstabilized component.

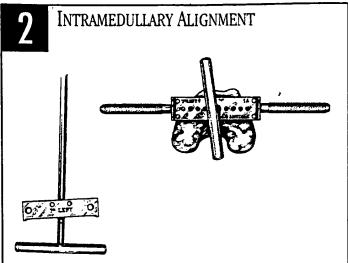
Metal base is inset into the cortical bone.

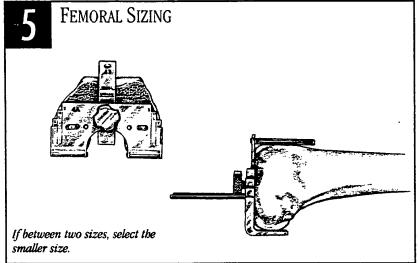


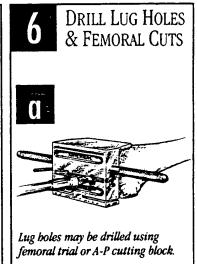
Dovetail locking mechanism allows convenient anterior loading, while the tibial eminence and angled tibial surfaces promote femoral rollback.

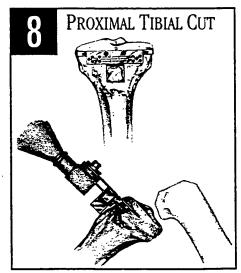
FEMORAL & TIBIAL PREPARATION

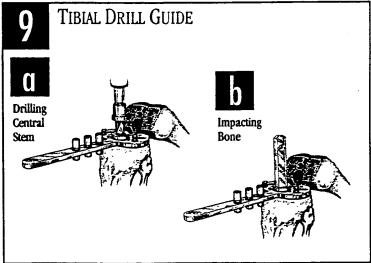




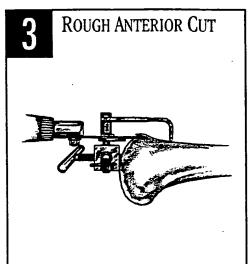


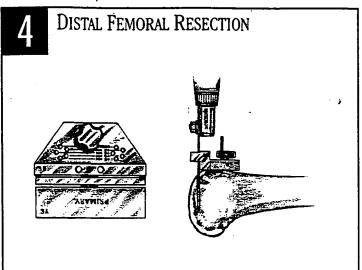


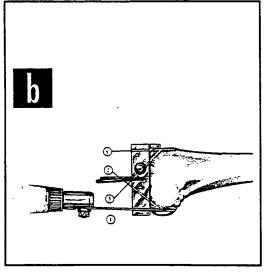


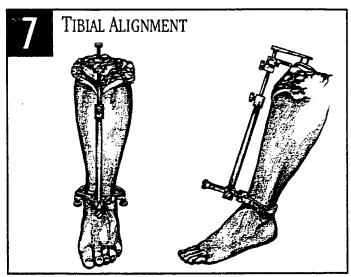


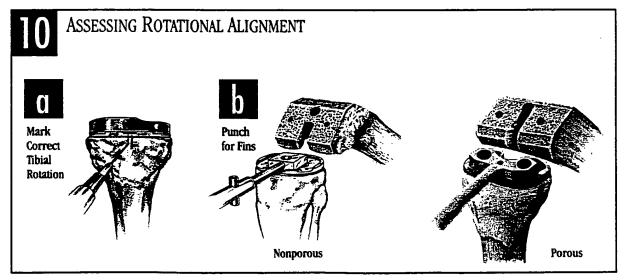
FOR THE POSTERIOR-STABILIZED KNEE, TURN TO PAGE 8



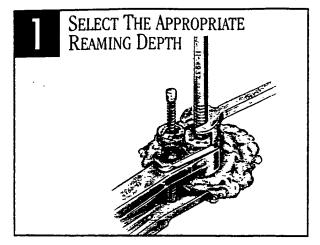


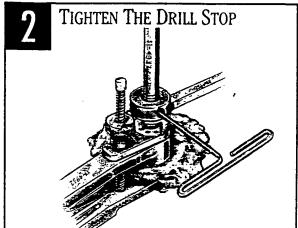


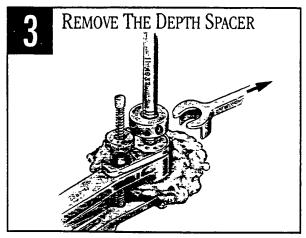


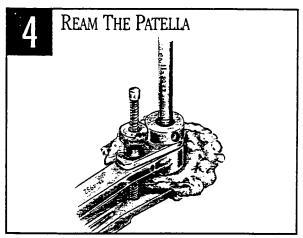


BICONVEX PATELLAR PREPARATION

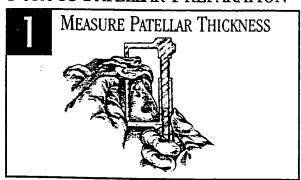


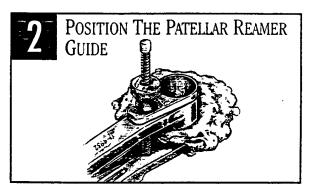


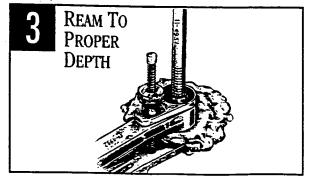


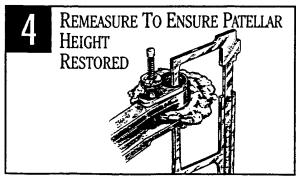


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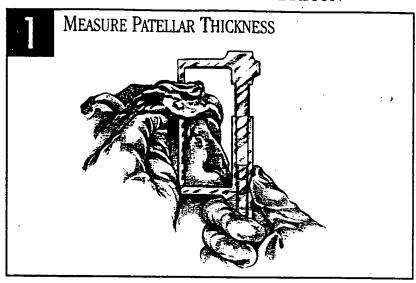


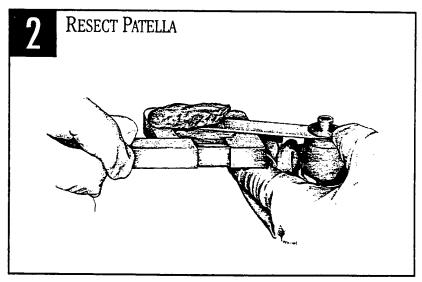


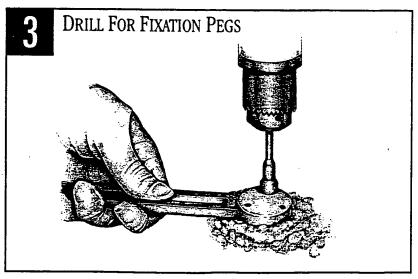




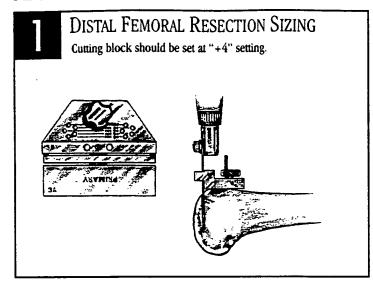
RESURFACING PATELLAR PREPARATION

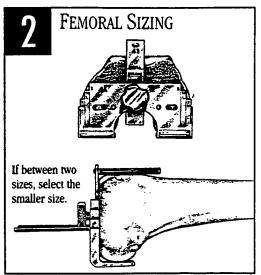


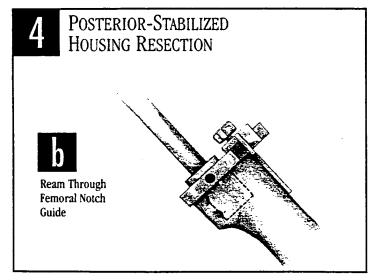


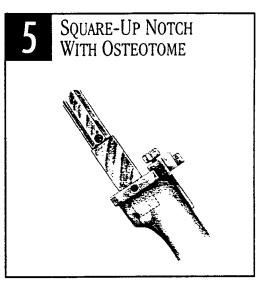


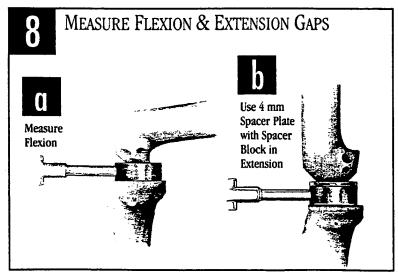
ADDITIONAL STEPS FOR THE POSTERIOR-STABILIZED FEMORAL CUTTING

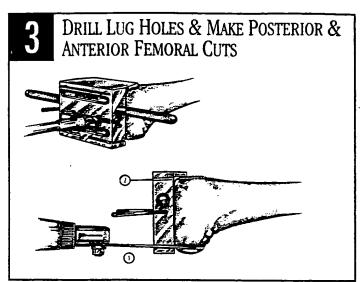


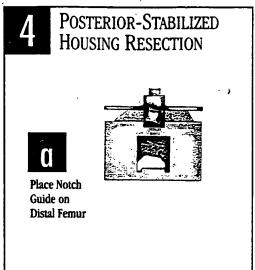


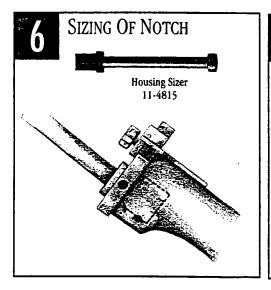


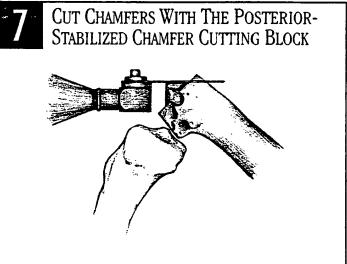












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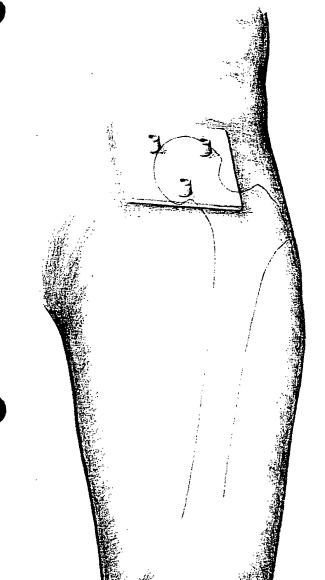


Figure 1

THE GENESIS TOTAL KNEE SYSTEM Primary Surgical Technique

PATIENT PREPARATION

Place a radiographic marker over the femoral head of the patient and confirm its position by an X-ray immediately preoperatively (Figure 1). The marker will allow intraoperative determination of the mechanical axis of the limb. Perform a standard surgical scrub and iodoform forepainting of the extremity, with placement of a tourniquet high on the thigh. Utilize sterile draping of the extremity. Place a nonbulky drape around the foot and ankle so that the bony anatomy can be palpated when using the tibial guide.

SURGICAL APPROACH

Exsanguinate the limb and inflate the tourniquet to the appropriate level. Make a straight longitudinal incision just medial to the midline of the knee, beginning four inches proximal to the superior border of the patella, and ending at the level of the tibial tuberosity (Figure 2). Carry the dissection through the subcutaneous tissues to the prepatellar bursa. Divide the prepatellar bursa and elevate its flaps medially and laterally. Make a medial parapatellar capsular incision 3/8" from the medial edge of the patella, extending proximally between the interval of the lateral edge of the vastus medialis and the rectus tendon (Figure 3). Splitting of the tendonous fibers rather than cutting through muscle will allow a better repair of the extensor mechanism.

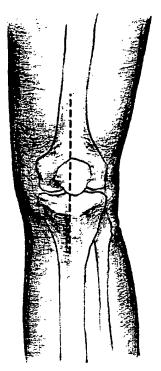
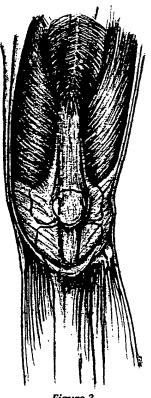


Figure 2



Attempt eversion and lateral dislocation of the patella. Further proximal dissection may be necessary if the soft tissues are tight. Evert the patella and flex the knee to 90° (Figure 4). Routine tissue cultures and biopsies for histological evaluation are performed at the discretion of the surgeon.

Sharply separate the deep portion of the medial capsule from the tibia to the midline posteriorly. Preserve the superficial medial collateral ligament and pes anserinus ligament attachments. Release the lateral epicondylopatellar ligament to mobilize the patella and expose the lateral compartment of the knee. Excise or preserve the fat pad as necessary to visualize the anterior aspect of the tibia adequately. Remove all osteophytes from the tibial plateau, femur, and intercondylar notch to allow visualization of the true anatomy. If osteophytes are not removed, it may result in errors in jig placement. Excise the remnants of the menisci and divide the anterior cruciate. Preserve the posterior cruciate ligament. If synovitis is present, perform a synovectomy.

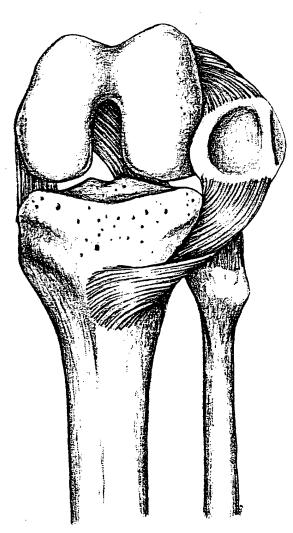


Figure 4

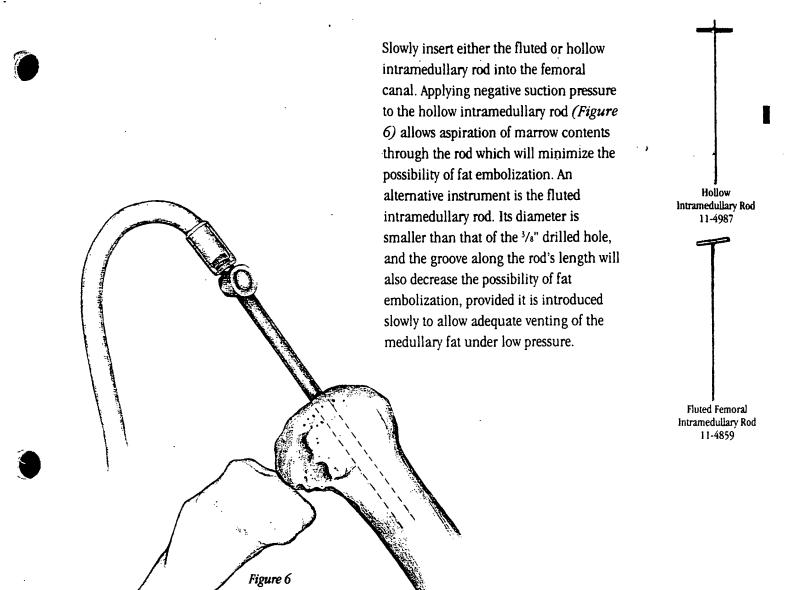
FEMORAL PREPARATION

Step 1 — Alignment

Place retractors under the medial and lateral collateral ligaments adjacent to the femoral epicondyles, so that the distal articular surface of the femur is fully exposed. The intercondylar notch should be easily defined after removal of the osteophytes, and you should be able to see the posterior cruciate ligament's femoral attachment. Make a 9.5 mm drill hole just above the posterior cruciate's femoral attachment (Figure 5). Deepen the hole with the 3/s" drill bit so that the intramedullary canal of the femur can be easily identified and the intramedullary rod can be seated. The drill bit should be angled slightly laterally in the direction of the femoral shaft to avoid medial cortical penetration.

Figure 5





Instrument #1A



Femoral Alignment Guide

11-3797

11-3798

11-3799

Instrument #1B



3° External Rotation Guide 11-3794



Neutral Rotation Guide 11-3793

Insert either the hollow or fluted intramedullary rod through the selected distal femoral alignment guide [Instrument #1A] (Figure 7). The option of a 5°, 6°, or 7° valgus alignment block is available. When operating on the left knee, "left" should be facing anteriorly. When operating on the right knee, "right" should be facing anteriorly. The surgeon has the option of neutral rotation or 3° of external rotation. When 3° of external rotation is desired, assemble the 3° external rotation guide [Instrument #1B] to the intramedullary alignment guide locking it into place with the thumb screw. When operating on the left knee, "left" should be facing the surgeon. When operating on the right knee, "right" should be facing the surgeon. When using the 3° external rotation guide, the assembly is in 3° of external rotation when there is an equal amount of medial and lateral posterior condyle. When neutral rotation is desired, assemble the neutral rotation guide [Instrument #1B] to the intramedullary alignment guide. Rotate the distal femoral alignment guide into neutral rotation based on the posterior femoral condyles. When using the neutral rotation guide, the assembly is in neutral rotation when there is an equal amount of medial and lateral posterior condyle exposed posteriorly. (It is very important to precisely set rotational alignment at this time because all subsequent cuts will reference this step.)

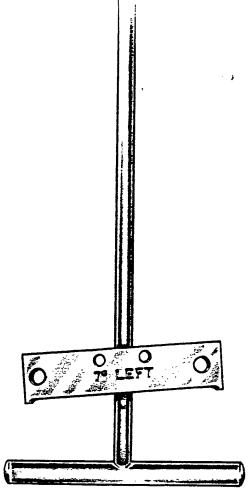
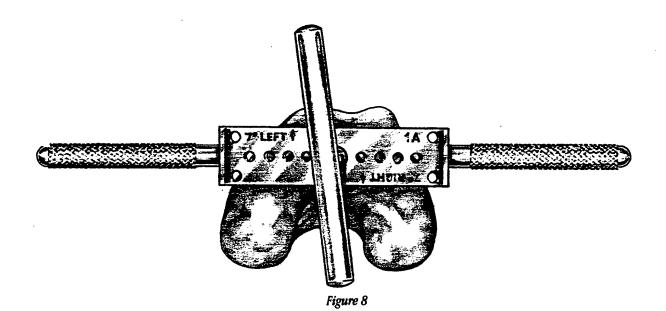


Figure 7

Insert the intramedullary rod into the intramedullary canal and secure the assembly onto the distal femur by inserting bone spikes or 1/8" pins into the holes provided on the medial and lateral surface of the guide (Figure 8). For additional stability, you may use a 1/8" drill or pin through the angled holes on the side of the assembly. The T-handle and alignment guide may be removed or left in place for additional stability.





Instrument #2



Femoral Cutting Block with Stylus 11-3782

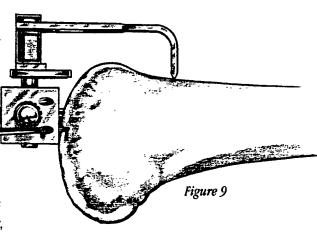


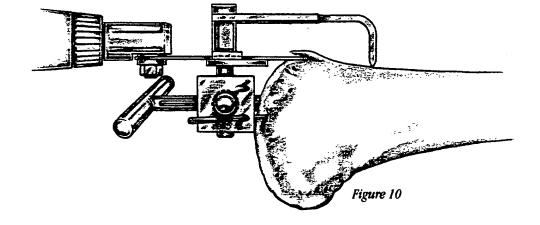
Sawblades: Stryker 11-4551 3M 11-4553 New Attachment Isco-Hall 11-4542 New Attachment Stryker 11-4549

Step 2 — Anterior Resection

Attach the anterior femoral cutting block [Instrument #2] to the intramedullary alignment block. Lower the jig until the anterior stylus arm touches the lateral anterior cortex (Figure 9). Secure the cutting block with a thumb screw or handle. Use a GENESIS sawblade through the slot to resect the anterior cortex (Figure 10). With the block positioned in this manner, the cut will remove

the anterior condyles flush with the anterior cortex of the femur and will minimize the chance of anterior notching. This cut will be modified by the anterior-posterior cutting blocks. However, it must be accurate for placement of subsequent cutting blocks. Knee anatomy varies from patient to patient. If you feel that excessive bone will be taken by this resection and that the femur will be notched, readjust the block before resecting. Remove the anterior femoral cutting block, leaving the intramedullary femoral alignment guide in place.





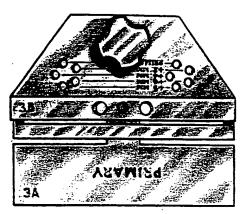


Figure 11

Step 3 — Distal Resection

Assemble the distal femoral cutting block by sliding the resection stylus [Instrument #3A] into the distal femoral cutting block [Instrument #3B] (Figure 11). Slide the resection stylus into the cutting block until it stops. This will ensure that 7.5 mm of distal bone, the thickness of the implant, is removed. Tighten the thumb screw. Drill 1/8" pins through the fixation holes labeled "primary." For additional stability, you may utilize the angled fixation holes on the side of the block (Figure 12).

Instrument #3A

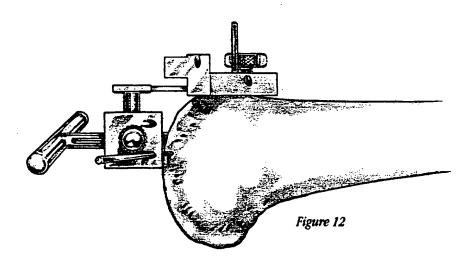


Distal Femoral Resection Stylus 11-3783

Instrument #3B



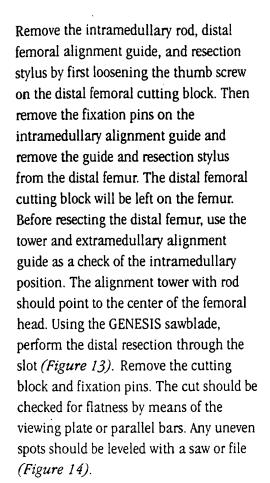
Distal Femoral Cutting Block 11-3784

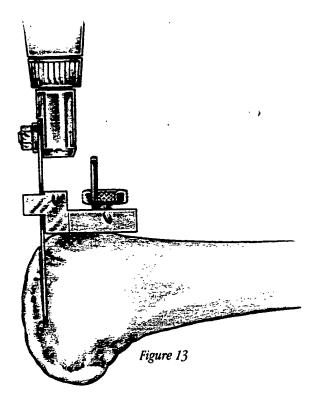




Extramedullary Alignment Tower 11-4667

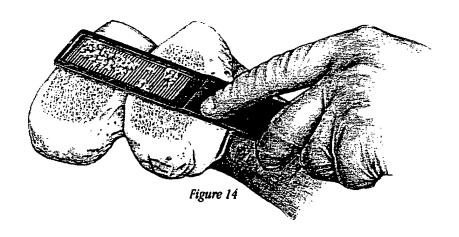
Extramedullary Alignment Guide Rod 11-4861



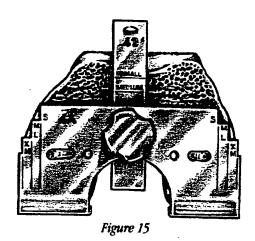




Parallel Bars 11-4886



Femoral File 11-4894



Step 4 — Sizing

Use the sizing guide to determine the anteroposterior size of the distal femur so that the size of the appropriate femoral implant can be chosen. Place the femoral sizing guide [Instruments #4A & 4B] onto the distal femur (Figure 15). The feet of the sizing guide should touch the posterior condyles (Figure 16). In some cases, the proximal tibia may need to be cut first before the sizing guide can be properly positioned. Slide the stylus arm down until it touches the flat cut anterior cortex. Read the indicated size. If the guide falls between two sizes, the smaller should be chosen. The sizing guide has steps on the medial and lateral sides to indicate medial-lateral coverage provided by each size implant.

Instrument #4B

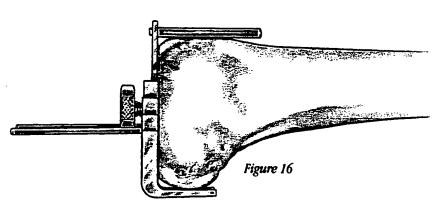


Femoral A-P Sizing Guide Stylus 11-3786

Instrument #4A



A-P Sizing Guide 11-3785



Step 5 — Finishing Cuts

Select the appropriate anterior-posterior cutting block [Instrument #5] as indicated from the sizing guide. Place the

block on the flat cut surface of the distal femur with the anterior plate flush against the flat anterior cortex. This block must be centered if lug holes are drilled at this

time (Figure 17). To secure the block, drill '/8" pins into the angled holes on the side of the block (Figure 18). While drilling, hold the block flat against the distal femur with the optional handles.

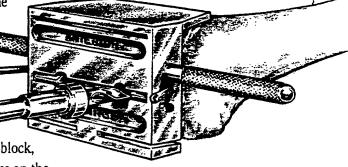
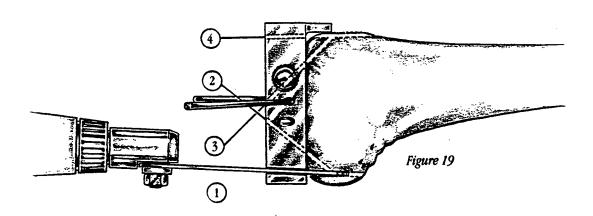


Figure 17

Begin the finishing cuts with the posterior resection (*Figure 19*). I cut the posterior chamfer, anterior resection, and finally the anterior chamfer.





Instrument #5

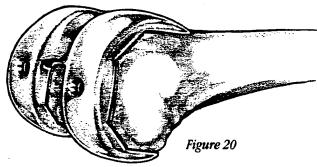


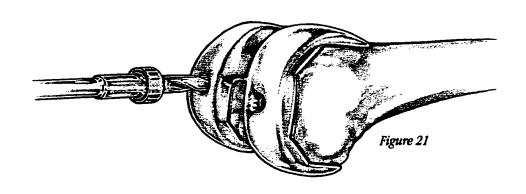
A-P Cutting Block 11-3787 through 11-3792

Step 6 — Lug Holes

You may drill the lug holes with either the A-P cutting block or the femoral trial. Before fixing either to the distal femur, ensure it is centered (Figure 20). If utilizing the femoral trial, select the appropriate size as determined by the sizing guide and seat it on the distal femur. Use the ⁹/₃₂" lug drill to drill for the lug holes (Figure 21). Drill to the depth provided by the stop on the drill.













ibial Cutting Blocks 0° – 11-4663 3° – 11-4665





11-4660

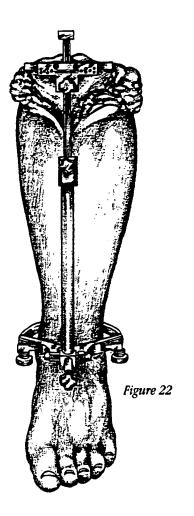
TIBIAL PREPARATION

Acutely flex the knee and subluxate the tibia forward. Use a wide blade Hohman or similar blunt retractor, carefully placed in the intercondylar notch, to subluxate the tibia anteriorly. Be careful not to damage the distal femur, especially in osteoporotic patients. Retraction should be gentle, with careful attention to the patellar ligament attachment on the tibia to prevent patellar tendon avulsion.

At this point, the surgeon has the choice between extramedullary and intramedullary alignment. If intramedullary is chosen, turn to page 26.

Tibial Extramedullary Alignment Method

The surgeon has the choice between a proximally spiked fixation rod and a nonspiked proximal rod. If the proximally spiked rod is selected, slide the rod through the slotted or nonslotted tibial cutting block. If the nonspiked proximal rod is utilized, slide the chosen tibial cutting block over the top until it hits the stop. Both the slotted and nonslotted cutting blocks are available with 0° or 3° posterior sloped cut. The Cruciate Retaining insert slopes 4° anterior to posterior. Using the 3° posterior sloped cutting block, a total slope of 7° is achieved. The rod is then inserted in the alignment sleeve which is attached to the ankle clamp. After locking the ankle clamp in the open position, place the assembly over the anterior crest of the tibia (Figure 22). The distal portion of the tibial assembly should lie over the center of the tibia which is medial to the center of the ankle. To secure the ankle clamp, depress the button on either side of the ankle clamp.



S U R G I C A L T E C H N I Q U E

The ankle clamp allows the surgeon to offset the distal end of the alignment guide up to 8 mm toward the medial side to allow alignment over the center of the talus. An offset of 8 mm minimizes the chance for a varus cut. Extend the proximal portion of the tibial assembly up over the proximal tibia. Impact the long spike into the proximal tibia at a point just anterior to the tibial spine. Adjust the position of the distal portion of the rod assembly until the rod is parallel to the mid-coronal plane of the tibia to ensure that the tibial cut is perpendicular to the tibial axis in all planes. The extramedullary alignment tower and rod can be used as a method of checking this alignment. (If the cutting plane is in varus or valgus, the distal 8 mm offset can be fine-tuned at this time to ensure correct alignment of the tibial cut.) If a posterior-sloped cut is desired, adjust the position of the distal portion of the assembly to the desired angle (no more than 5°), or use the 3° posterior sloped cutting block. Impact the shorter spike on the proximal portion of the assembly into the tibia (Figure 23).

Assess the compartments of the tibia to determine the lowest point of the tibia. In cases of large bone loss on the medial or lateral compartment, it may be necessary to adjust the cutting level proximal to or above the level of maximum bone loss and to subsequently bone graft the defect or use an augmentation wedge. Raise the tibial cutting block to its most proximal position on the extramedullary alignment rod.

Figure 23

Please turn to page 28 to bypass the Tibial Intramedullary Alignment Method and continue with the suggested surgical approach.

Extramedullary Alignment Rod 11-4861

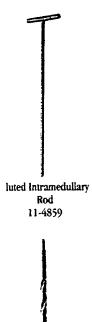


Extramedullary Alignment Tower 11-4667

25

fibial Intramedullary Alignment Assembly 11-4599





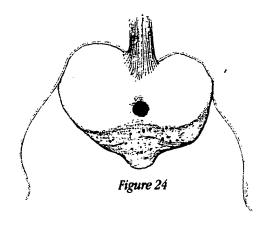
moral Drill-9.5 mm 11-4947

Tibial Intramedullary Alignment Method

Begin by making a conservative rough cut on the proximal tibia by removing only the prominent peaks thereby leaving a flatter surface. Place the correctly sized tibial drill guide onto the proximal tibia and make a mark through the drill guide with methylene blue (Figure 24).

Make a pilot hole with a gouge on this methylene blue dot on the surface of the tibial plateau. The hole should lie in the midline mediolaterally, and approximately 7 to 10 mm anterior to the midline of the surface anteroposteriorly. CAUTION: Do not make the pilot hole directly in the anteroposterior midline. The posterior aspect of the tibia slopes forward and an intramedullary rod inserted through this point will abut against the inner posterior cortex. Enlarge the pilot hole using the 9.5 mm femoral drill.

Place the intramedullary rod through the tibial intramedullary alignment assembly and tighten the locking screw. Advance the intramedullary rod down into the tibia (Figure 25). Testing has shown that the rod will meet firm resistance at the level of the previous epiphyseal scar of the distal tibia. The rod must be seated at least to this level to gain adequate purchase and stability.



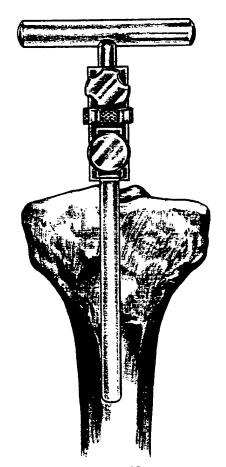
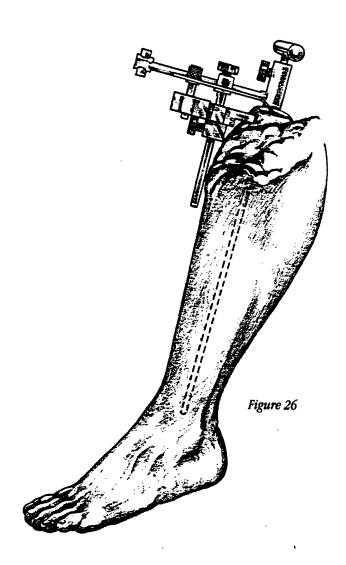


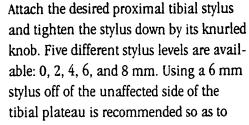
Figure 25

Place the slotted or nonslotted cutting block on the outrigger of the tibial intramedullary alignment assembly. Raise the tibial cutting block to its most proximal position and tighten the locking screw (Figure 26).



Note: While the illustrations show extramedullary alignment guides, the technique here is the same for either intramedullary or extramedullary.

Tibial Stylus 11-4668 11-4671 11-4672 11-4673 11-4674



TIBIAL PREPARATION (RESUMED)

allow the use of polyethylene that is over 6 mm in thickness.

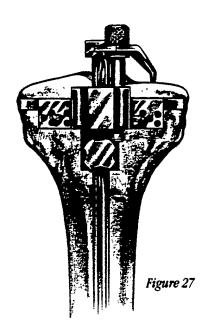


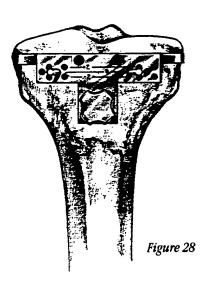
There are two holes in the tibial block on either side of the extramedullary alignment rod. Insert a '/8" pin into one hole on each side of the tibial rod assembly to affix the tibial cutting block to the anterior surface of the tibia (Figure 27). Take care to retract the patellar ligament laterally, so that it is not impaled by a drill.

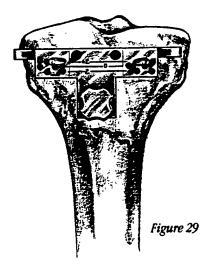


Tibial Cutting Block, Slotted 0° - 11-4664 3° - 11-4666

Once the tibial cutting block is securely affixed to the tibia, the tibial stylus and alignment assembly can be removed leaving only the tibial cutting block (Figure 28). Optional angled holes on either side of the tibial cutting block may be used for additional stability. Using the anterior reference guide, carefully compare the level of the tibial cutting surface to the bone deficiency on the tibia. If it appears that too little bone is going to be removed, the block can be adjusted to remove 2 mm more bone (Figure 29). If it appears that too much bone will be removed, the block can be adjusted to remove 2 mm less bone. Once the correct height of the tibial cutting block has been selected, check the orientation of the tibial cutting block in the varus-valgus plane.







S U R G I C A L T E C H N I Q U E

This can be done by attaching the extramedullary alignment tower to the tibial cutting block and placing a long extramedullary alignment rod through the tower. The rod should center on the center of the talus in both the coronal and sagittal planes. If the orientation of the tibial cutting block is correct, the tibia is ready to be cut.



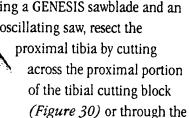
Tibial Viewing Plate

11-4920 11-4922

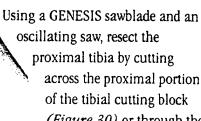
11-4924 11-4926

11-4927

Place a wide PCL retractor vertically into the tibia just anterior to the posterior cruciate ligament. The retractor will protect the posterior cruciate ligament during osteotomy of the tibia.



slot. Keep the sawblade flush with the tibial cutting block to ensure a flat cut. It may be necessary to remove the tibial cutting block and pins to complete the posterior portion of the cut. Using a reciprocating saw, cut a small notch posteriorly on each side of the retractor to remove the cut portion of the tibial bone. The remaining bone can be removed with a rongeur to allow seating of the tibial component. This will prevent inadvertent injury to the posterior cruciate ligament. Check the cut surface of the tibia to be sure that it is flat using a straight edge or the tibial viewing plate. Level any high spots with a saw or a file. Size the tibia using the tibial viewing plate (Figure 31).



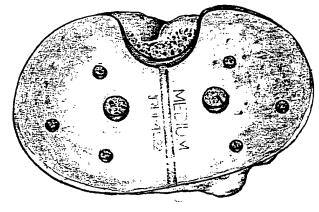


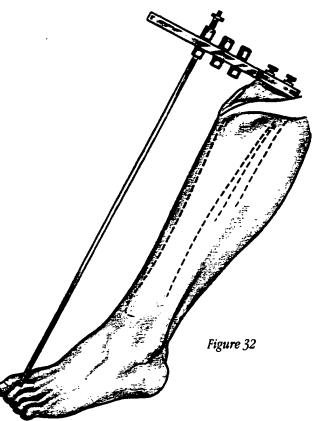
Figure 30

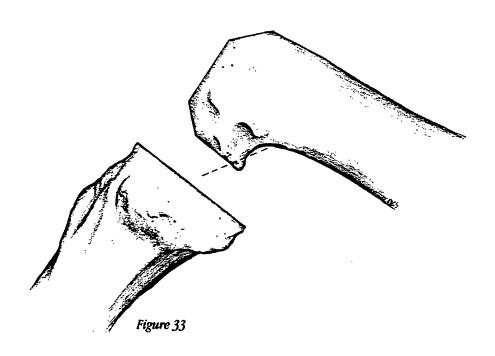
Figure 31



Place the tibial drill guide onto the cut surface of the tibia. The handle of the drill guide should be aligned with the medial quarter of the tibial tubercle. Place a long extramedullary alignment rod through the handle (Figure 32). The alignment rod should center on the distal tibia in the coronal and sagittal planes, thus assuring that the tibial cut is at 90° to the long axis of the tibia.

Posterior femoral osteophytes are a frequent problem. These should be removed with a curved osteotome to prevent their impedance in flexion. The posterior osteophytes, if left remaining, will also limit extension because of increased tension on the posterior capsule (Figure 33).

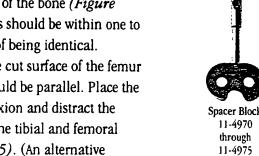




Assess soft tissue balance in both flexion and extension. Place the leg in full extension, but not hyperextension, and

manually distract the tibia from the femur. Using a ruler, measure the medial and lateral soft tissue spaces

between the ends of the bone (Figure 34). These spaces should be within one to two millimeters of being identical. Consequently, the cut surface of the femur and the tibia should be parallel. Place the knee in 90° of flexion and distract the femur. Measure the tibial and femoral spaces (Figure 35). (An alternative method is to use the spacer block to assess the flexion and extension spaces.) Again, the gap should be of similar size on the medial and lateral side. The flexion space and the extension space should be the same. If the spaces are not the same, then additional soft tissue releases or bone resection will be required. This is discussed further in Appendix C on page 59.



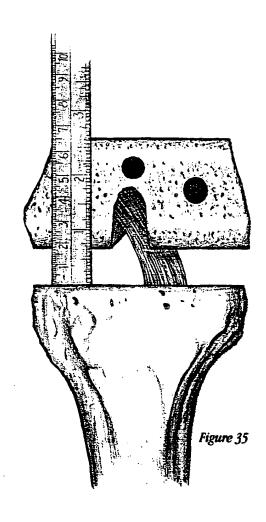


Figure 34

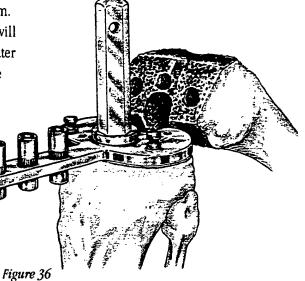






TIBIAL STEM PREPARATION

Place the proper size tibial drill guide with an 11 mm tibial collet onto the surface of the tibia. The handle should be aligned with the medial quarter of the tibial tubercle. Secure the drill guide with two pins. Drill the subchondral bone with the 11 mm tibial drill to the stop. Use the 11 mm tibial punch to impact the remaining bone (Figure 36). The diameter of the tibial stem is 12 mm. Using the 11 mm drill and punch will allow for a 1 mm press fit. If a greater cement mantle is desired, select the 13 mm tibial collet.



TRIAL INSERTION

Flex the knee. Place a wide Hohman or similar retractor posteriorly and subluxate the tibia anteriorly. Select the appropriate tibial trial base and set it on the proximal tibia (Figure 37). Remove the Hohman retractor and reduce the tibia. Select the appropriate size of femoral trial component, seat it on the distal femur, and impact it into position. If a posterior-stabilized component is used, remove the lugs on the femoral trial component.

Assemble the conversion module trial on

the femoral trial component. Position the articular insert trial onto the tibial base.



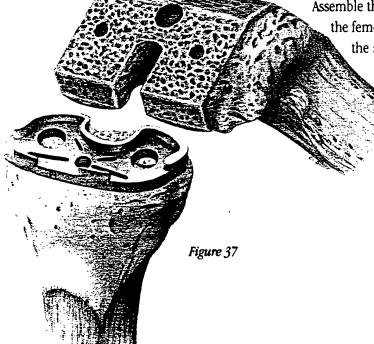
Femoral Trial 11-4414



Tibial Articular Insert 71-4513



Tibial Base Trial 71-4501





Patellar Reamer Guide 11-4932





ellar Reamer Shaft 11-4937



Biconvex Patellar Reamer 1-4929, 11-4934, 11-4936





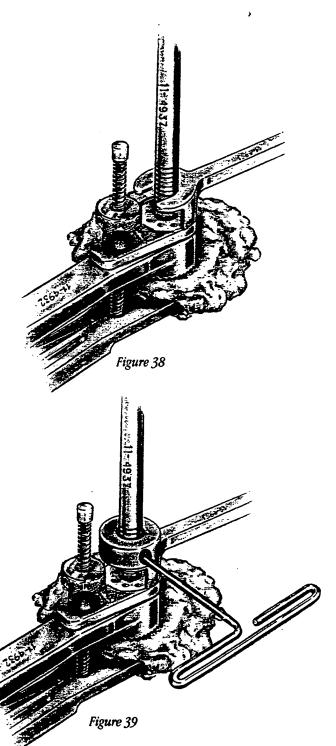
T-Handle Allen Wrench 26-0291

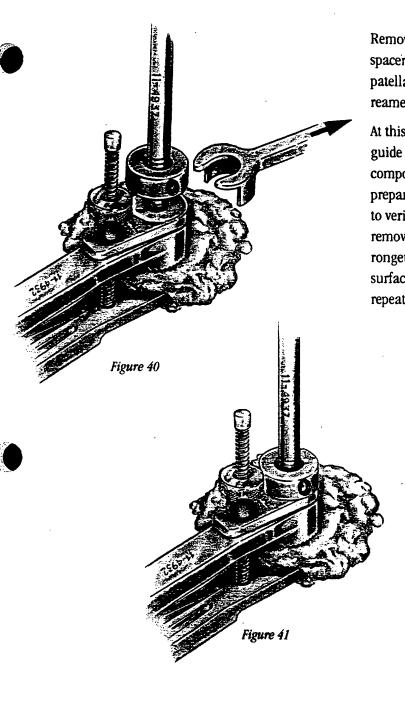
PATELLAR PREPARATION

There are three separate options for patellar preparation. They include the Biconvex Patella, Porous Patella, and Resurfacing Patella. The three separate techniques follow.

Biconvex Patella

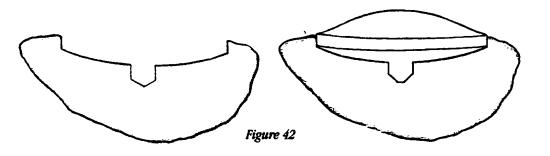
The goal of resurfacing the patella is to reapproximate the natural thickness of the patella by replacing the bone removed with an implant that restores the patella to its original height. The patellar reamer guide should be clamped to the everted patella. Measure the patella thickness. Position the calipers so that one end is through the opening of the guide and against the anterior surface of the patella or the inferior surface of the guide. Bring the opposite end of the calipers to rest on the highest point of the articulating surface of the patella. Read the height, in centimeters, off the scale on the calipers. Choose the appropriate size biconvex patellar component, keeping in mind that the sizes are 13 mm, 14 mm, and 15 mm in thickness and 29 mm, 32 mm, and 35 mm in diameter for Extra-Small, Small, and Medium respectively. Place the patellar drill stop on the patellar reamer shaft. Attach the appropriate size biconvex patellar reamer to the reamer shaft. Select the appropriate end of the biconvex patellar depth spacer and place this on the reamer guide so that the spacer rests on the guide, not on the reamer head or shaft (Figure 38). Bring the patellar drill stop down to rest on the top of the patellar depth spacer. Tighten the patellar drill stop locking screw down by using the ³/₁₆" T-Handle Allen wrench (Figure 39). Note: it is important to make sure that the patellar reamer shaft is perpendicular to the reamer guide. This will ensure that the depth stop is placed at the correct height.





Remove the biconvex patellar depth spacer (Figure 40) and ream until the patellar drill stop contacts the patellar reamer guide (Figure 41).

At this point, with the patellar reamer guide in place, the trial patellar component can be placed into the prepared bone and the caliper can be used to verify that enough bone has been removed (Figure 42). If necessary, use a rongeur to remove any prominent patellar surface around the trial. Irrigate the joint repeatedly to remove any debris.



Patellar Cement Clamp 11-4946

Porous Patella

Remove any peripheral patellar osteophytes. Make a methylene blue dot in the center of the patella. Position the patellar clamp with the dot in the center of the drill sleeve. The back of the clamp is seated on the anterior surface of the patella. Tighten the clamp. If a Small or Extra-Small patellar implant will be used, place the appropriate collet into the guide. Use the caliper to determine the thickness of the patella (Figure 43). The goal is, with the patella in place, to reproduce the thickness found prior to reaming. This technique may need to be modified in cases of severe patellar bone erosion. Ream through the clamp (Figure 44). This will create a recess in the patella to accept the patellar implant (Figure 45). Periodically insert the patellar trial implant and recheck the thickness so that over-reaming can be avoided. When the proper depth of reaming has been achieved, remove the reamer and patellar clamp. Leave the trial patellar implant in place to protect the bony rims of the channel (Figure 46). If necessary, use a rongeur to remove any prominent patellar surface. Irrigate the joint repeatedly to remove any debris.

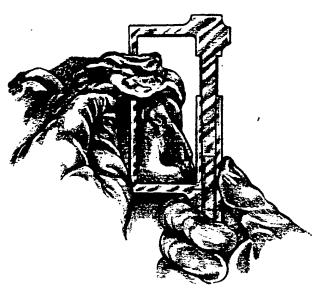
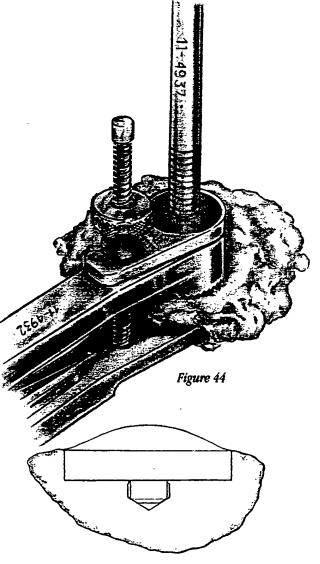


Figure 43



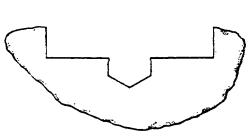


Figure 45

Figure 46

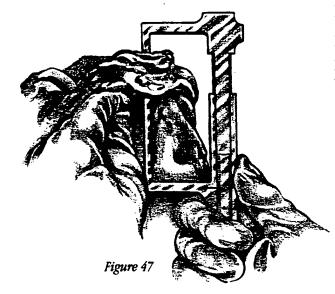


Figure 48

Resurfacing Patella

Determine which size of resurfacing patella will best fit the patient's anatomy. The resurfacing patellar implant is available in diameters of 32 mm (small), 35 mm (medium), and 41 mm (large). Measure the patella thickness with a caliper (Figure 47).

Note: If the small or medium size is chosen, the patellar reamer guide with the appropriate resurfacing reamer may be used to prepare for the implant instead of the technique described above. If a large size is chosen, the above technique must be followed.

Place the patellar resection guide so that its jaws are located proximally and distally from the patella, even with the soft tissue attachments of the quadriceps proximally and patellar ligament distally. It may be necessary to remove a small amount of bone at the inferior pole of the patella from its articular surface to seat the clamp. Orient the clamp so that the thick median ridge of the patella will be

> resected. The usual depth of resection is even with the subchondral bone of the lateral facet of the patella. Using a ruler, measure the amount of bone to be removed from the level of the patellar

cutting guide, to the most prominent portion on the median ridge (Figure 48).

The amount of bone removed should be equal to the thickness of the patellar implant - 7.5 mm, not including the pegs.



11-4943



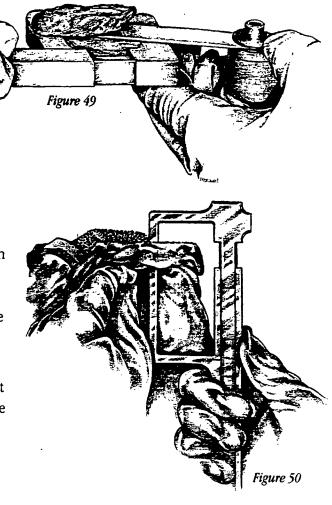
Resection Guide 11-4938

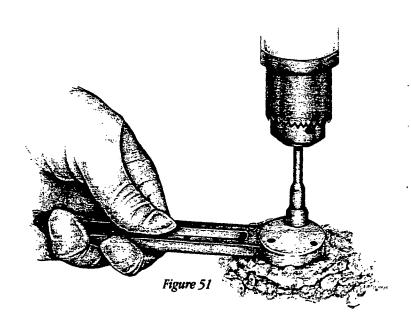




Cut the patella with an oscillating saw (Figure 49). Remove the patellar resection guide. Use a caliper to be sure that the patella is cut evenly anteriorly, posteriorly, medially, and laterally (Figure 50). If there is asymmetry in the bone cut, it should be corrected using a rasp or saw. A flat surface on the patella is ideal. The remaining amount of patellar bone, when added to the thickness of the patellar implant, should equal the original thickness of the patella (prior to any bone cuts).

Place the patellar drill guide onto the cut surface of the patella. Choose the size that provides optimal bone coverage. Using the patellar drill guide, drill the holes for the patellar fixation pegs (Figure 51).

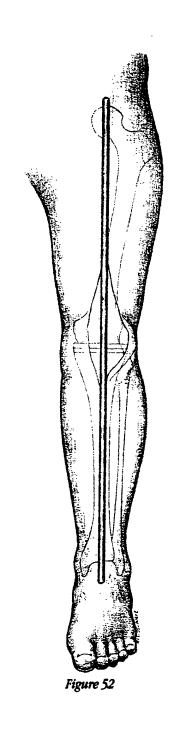




ALIGNMENT VERIFICATION

Manually seat the trial patellar component. With the trial prosthesis in place, gently perform a trial range of motion to ascertain proper patellar tracking. Assess the rotational orientation of the tibial base. Improper rotational orientation may result in improper femoral and/or patellar tracking. The optimal alignment is with the center line of the trial even with the tibial tuberosity.

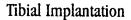
With the knee in full extension, the implant should be rotationally symmetric with the femur. Check the mechanical axis of the limb using the long alignment rod (Figure 52). The proximal end of the rod is centered on the radiographic marker over the femoral head, and the distal portion of the center of the talus. The rod should pass over the center of the knee. Once correct rotational alignment has been chosen, mark the tibia with either methylene blue or cautery. The rotational mark on the trial component will allow marking the tibia so that the actual component is placed in the same orientation. Each implant size is determined by the shape and size of the patient's bones. Any combination of implants is permissible. The largest size of tibial component that completely covers the tibial surface to the cortical margin should be chosen. Overhang of the component on the medial aspect of the tibia must be avoided or impingement on the medial collateral ligament will cause pain.





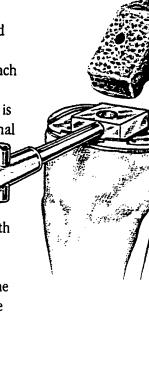
FINAL TIBIAL PREPARATION FOR NONPOROUS COMPONENT

After checking component tracking and knee stability throughout a range of motion, place the tibial cement fin punch through the posterior slots in the tibial trial. Ensure that the tibial component is correctly aligned with the prior rotational mark on the tibia (Figure 53). Remove the trials. If a cement mantle is desired, place the tibial drill guide on the cut surface of the tibia and secure it with two bone spikes, using the previously made holes. Replace the 11 mm tibial collet with a 13 mm tibial collet. Use the 13 mm tibial punch to enlarge the hole for the stem to provide an even cement mantle around the stem.



Cleanse the bony surfaces by pulsatile lavage irrigation. Subluxate the tibia forward by hyperflexing the knee, placing a hand on the posterior calf and pulling the tibia anteriorly. It is helpful to place a Hohman retractor or similar device posteriorly on the tibia to hold the tibia in an anteriorly displaced position.

Mix a package of acrylic cement and insert it into a cement gun. If a cement mantle has been prepared, insert the cement gun into the drill hole (Figure 54) and inject cement into the cut surface of the proximal tibia. Attach the tibial tray impactor/extractor on the tibial implant base plate. Impact the tibial implant base plate. Align the reference mark with the previously made mark on the anterior tibia to ensure proper rotational component orientation. Remove any extruded cement.



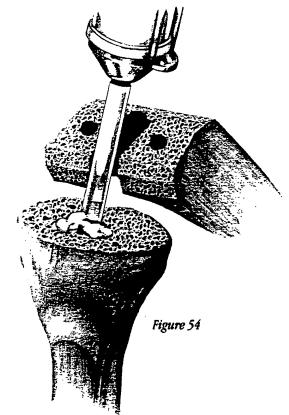


Figure 53



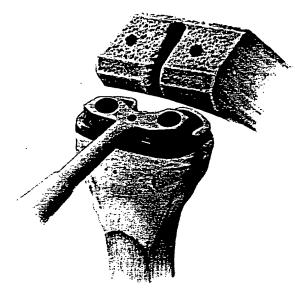


Figure 55

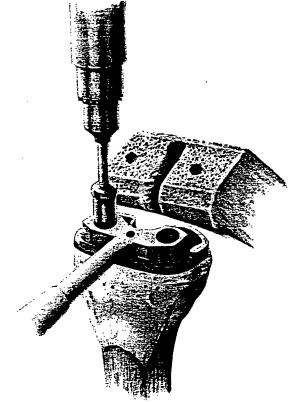


Figure 56

FINAL TIBIAL PREPARATION FOR POROUS COMPONENT

If the compression bone screws are to be used, take the proper size tibial fin punch/drill guide (Figure 55) and punch through the slots in the metal tibial trial. Drill through the guide with the compression bone screw drill (Figure 56). Remove the fin punch/drill guide. If the optional Flex-Lok pegs are to be used, then drill through the drill guide with the peg drill at this time. Remove the drill, drill guide, and metal tibial trial. As an alternative, if compression screws are used, you can drill the holes through the permanent base plate using the optional screw drill guide.

Implantation

Deflate the tourniquet and obtain hemostasis. Take care to check the posterior lateral corner of the knee. The lateral inferior genicular artery in this area is adjacent to the lateral meniscus and often is cut when exposing the tibia. Irrigate the knee. Re-exsanguinate the knee and reinflate the tourniquet.

Note: The use of this device is approved for cemented use only. Current cementing techniques should be used for all prepared surfaces.



Porous Fin Punch/Drill Guide 71-4608 71-4610 71-4612



Porous GENESIS Lag Screw Drill 71-4616



Tibial Flex-Lok Peg Drill 71-4622

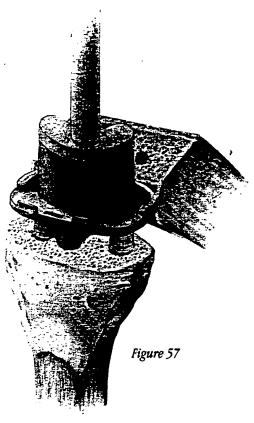
Compression Lag Screw Tap 71-4618

Use of Optional Flex-Lok Pegs

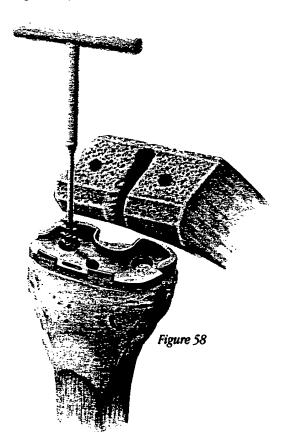
Insert two Flex-Lok tibial pegs on the permanent tibial base plate. Secure them to the base plate with the accompanying locking screws. Before impacting the base plate onto the tibia, finish preparing the tibia to accept the Flex-Lok pegs by impacting the chamfer punch into the holes to allow proper seating of the component. Impact the permanent implant into position (Figure 57).

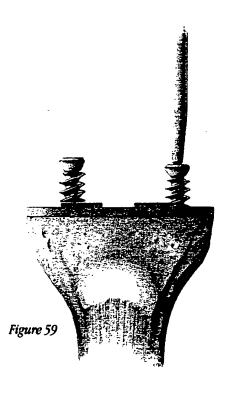
Use of Cancellous Compression Lag Screws

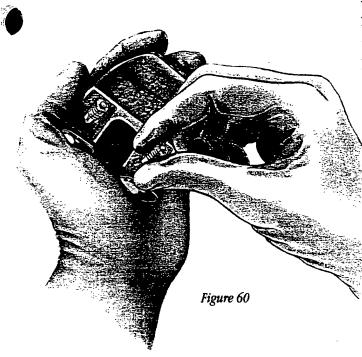
Remove the cement plugs from the tibial base with the slotted screwdriver and insert the permanent tibial base plate and impact until it is flush with the cut surface of the tibia. If the tibial bone is sclerotic, use the tap through the base plate for two to three threads (Figure 58). Insert the lag screws through the base plate into the tibia. Alternatively tighten each screw until the base plate is firmly compressed (Figure 59).











FEMORAL COMPONENT IMPLANTATION

Prepare the femur again with a pulsatile lavage. Mix another package of cement and, using the cement gun, place it onto the femoral surface.

Porous Femoral

If the optional Flex-Lok pegs are to be utilized on the femoral component, use the special torque limiting wrench provided to remove the metal lugs from the permanent femoral component. Insert a Flex-Lok peg on each of the studs and tighten by hand (Figure 60). THE OUS FEMORAL COMPONENT CANNOT

POROUS FEMORAL COMPONENT CANNOT BE USED WITH ANY OF THE CONVERSION MODULES.

Nonporous Femoral

If a posterior-stabilized component is used, remove the lugs from the femoral implant with the torque wrench. Assemble the conversion module on the femoral component and tighten the lugs back in place using the torque wrench. It is important to turn the torque wrench until you feel a break when tightening the femoral fixation lugs. This will ensure that 70 inch pounds of torque has been applied to the lugs. DO NOT APPLY BONE CEMENT BETWEEN THE MODULE AND FEMORAL IMPLANT.

Impact the femoral component onto the distal femur. With the tibial trial insert in place, place the femoral implant onto the femur with its pegs aligned with the peg holes. Impact the femoral implant into position. Remove any excess cement. Extend the knee to be sure the femoral implant is fully seated.





PATELLAR COMPONENT **IMPLANTATION**

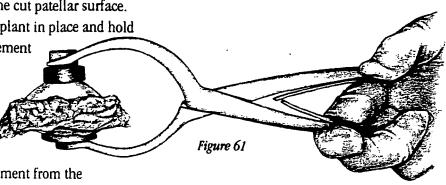
Inject cement onto the cut patellar surface.

Place the patellar implant in place and hold

it with the patellar cement clamp (Figure 61).

Remove any extruded cement. Once the cement

has hardened.



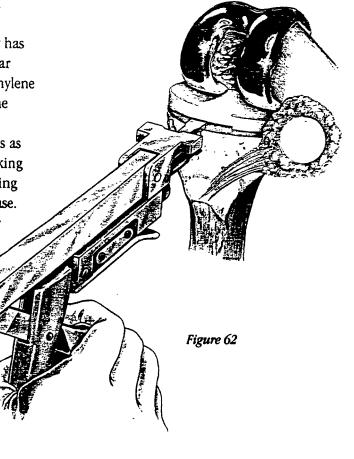
remove any excess cement from the femur or patella. With the trial articular insert in place, check the knee for stability and patellar tracking throughout a full range of motion. If patellar tracking is not satisfactory, perform a lateral retinacular release. Be careful to preserve the superior lateral genicular vessels.

ARTICULAR INSERT ASSEMBLY

Once satisfactory tracking and stability has been achieved, remove the trial articular insert and insert the permanent polyethylene articular insert from the front. Place the proper size insert into the base plate, pressing it posteriorly with your thumbs as far as possible. Be sure to align the locking mechanism on the insert with the locking mechanism on the permanent tibial base. Complete the seating with the articular insert assembly tool. Engage the inferior lip of the seating tool in the recess in the tibial component and lock into place. When properly attached to the base plate, the assembly tool will be at a downward angle. Squeeze the handle twice (Figure 62).

The articular surface should completely seat as the handle is released the second time.





CLOSING

Release the tourniquet and obtain hemostasis. Cleanse the knee thoroughly with the pulsatile lavage. Place two large suction drains within the knee and close the knee in layers. Nonabsorbable suture is recommended for closure of the fascial layer. Once the deep portion of the closure has been completed, flex the knee to be sure that a watertight closure has been obtained.

Close the subcutaneous tissues and skin. Primary would healing should be the goal and meticulous skin enclosure is essential. Place a sterile dressing, followed by an elastic bandage, over the wound. Radiographs of the knee in both the anterior-posterior and lateral projections should be obtained. Continuous passive motion may be utilized or motion may be delayed with the knee immobilizer, depending upon the preference of the surgeon.

POSTOPERATIVE CARE

The patient's drains are removed when drainage has ceased, usually within 48 hours. Quadriceps setting exercises may be done immediately postoperatively. Once the drains are removed, the patient begins ambulating and a supervised physical therapy program for range of motion is implemented. A knee immobilizer may be used during sleeping to encourage knee extension. The patient should use a walker or crutches until wound healing has occurred and muscle strength is recovered. This usually requires a period of six weeks. Weight bearing is performed to patient tolerance. When the patient can actively achieve full knee extension, use of the knee immobilizer can be discontinued. An outpatient program of physical therapy should continue for at least six weeks following hospital dismissal.

POSTERIOR-STABILIZED FEMORAL PREPARATION APPENDIXA

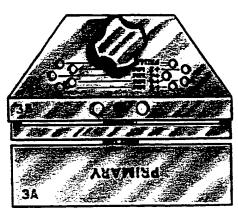


Figure 1

Distal Femoral Resection

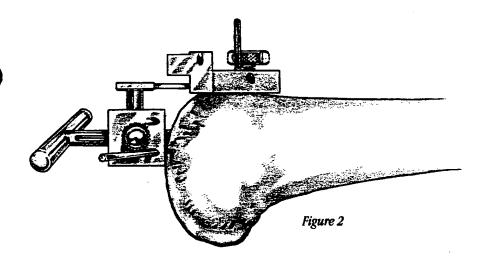
Assemble the distal femoral cutting block by sliding the resection stylus [Instrument #3A] into the distal femoral cutting block [Instrument #3B] (Figure 1). Slide the resection stylus into the cutting block until "+4" can be read. This will ensure that the proper amount of distal bone is resected. Tighten the thumb screw. Drill 1/8" pins through the fixation holes labeled "primary." For additional stability you may utilize the angled fixation holes on the side of the block (Figure 2).







Distal Femoral Cutting Block 11-3784

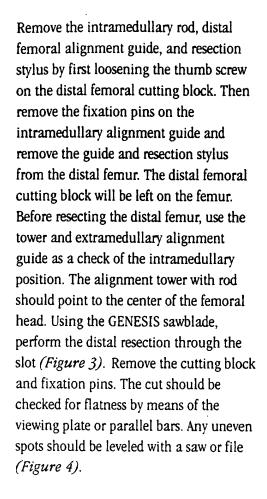


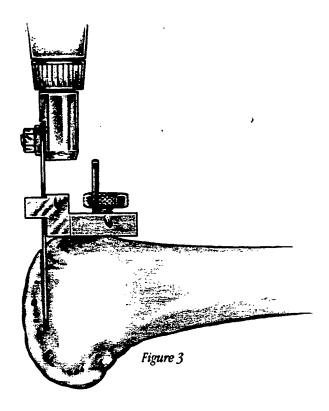
APPENDIX A POSTERIOR-STABILIZED FEMORAL PREPARATION



Extramedullary Alignment Tower 11-4667

Extramedullary Alignment Guide Rod 11-4861

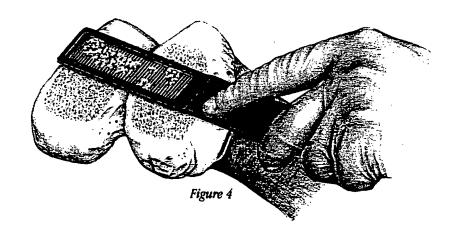




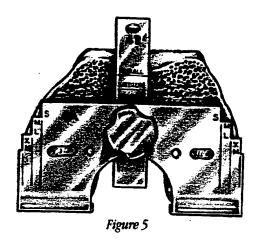


Parallel Bars 11-4886

Femoral File 11-4894



POSTERIOR-STABILIZED FEMORAL PREPARATION APPENDIX A



Femoral Sizing

Use the sizing guide to determine the anteroposterior size of the distal femur so that the size of the appropriate femoral implant can be chosen. Place the femoral sizing guide [Instruments #4A & 4B] onto the distal femur (Figure 5). The feet of the sizing guide should touch the posterior condyles (Figure 6). In some cases, the proximal tibia may need to be cut first before the sizing guide can be properly positioned. Slide the stylus arm down until it touches the flat cut anterior cortex. Read the indicated size. If the guide falls between two sizes, the smaller should be chosen. The sizing guide has steps on the medial and lateral sides to indicate medial-lateral coverage provided by each size implant.



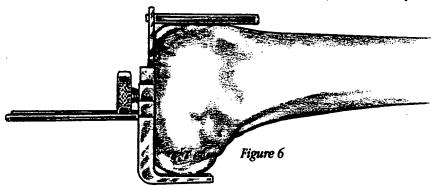


Fernoral A-P Sizing Guide Stylus 11-3786

Instrument #4A



A-P Sizing Guide 11-3785



APPENDIX A POSTERIOR-STABILIZED FEMORAL PREPARATION

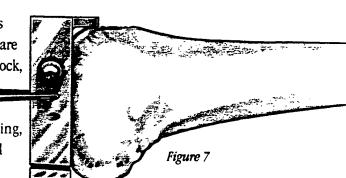
Anterior-Posterior Cuts

Select the appropriate anterior-posterior cutting block [Instrument #5] as indicated from the sizing guide. Place the block on the flat cut surface of the distal femur with the anterior plate flush against the flat anterior cortex. This

block must be centered if lug holes are drilled at this time. To secure the block,

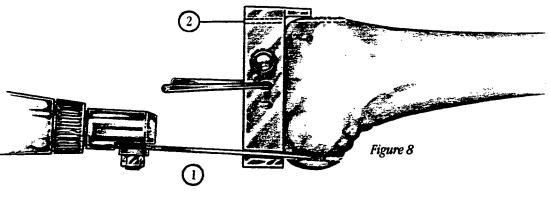
drill 1/8" pins into the angled holes on the side

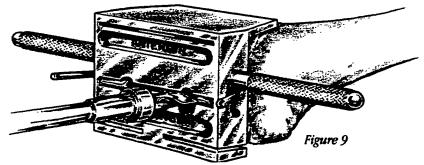
of the block (Figure 7). While drilling, hold the block flat against the distal femur with the optional handles.



Begin with the posterior resection (Figure 8). Use a GENESIS sawblade to cut through the posterior slot on the anterior-posterior cutting block, then perform the anterior resection. DO NOT MAKE CHAMFER RESECTION AT THIS TIME.

Utilize the ⁹/₃₂" lug drill to drill for the lug holes through the anterior-posterior cutting block. Drill to the depth provided by the stop on the drill (*Figure 9*).



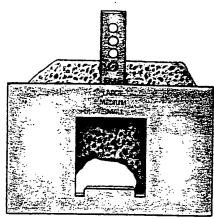


Instrument #5



11-3787 through 11-3792

POSTERIOR-STABILIZED FEMORAL PREPARATION APPENDIXA



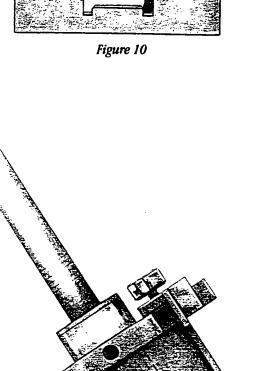


Figure 11

Posterior-Stabilized Housing. Preparation

Following removal of the A-P cutting block, attach the femoral notch guide to the distal femur by inserting the two posts into the distal femoral fixation holes (Figure 10). Be sure the component is flat and contacting the entire distal cut surface. Attach the posterior-stabilized reamer dome to the patellar reamer shaft. A blunt retractor may be placed posteriorly to prevent the reamer dome from contacting surrounding soft tissue. Prepare the distal femur by reaming in through the femoral notch guide until the stop on the reamer dome contacts the femoral notch guide (Figure 11). Remove the reamer.



Femoral Notch Guide 11-4811 11-4813



Posterior-Stabilized Reamer Dome 11-4818



11-4937

APPENDIXA POSTERIOR-STABILIZED FEMORAL PREPARATION



Posterior-Stabilized Housing Osteotome 11-4816



Posterior-Stabilized Housing Sizer 11-4815

A small amount of bone may remain anteriorly, medially, or laterally. If this bone is not removed, it could impinge

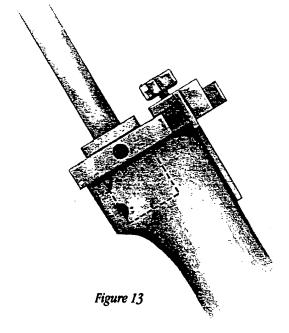
with the tibial eminence and compromise the kinematics



Figure 12

of the knee. An osteotome has been provided which precisely matches the interior dimensions of the femoral notch guide. Insert the osteotome to cut away any bone that may remain (Figure 12). A "stop" has been manufactured on the osteotome to prevent the osteotome from cutting too deep. When completed, the amount of bone removed will correspond to the dimensions of the conversion module's cam and the tibial eminence.

Verification of the correct depth is determined by inserting the housing sizer through the femoral notch guide. The housing sizer will only mate with the femoral notch guide in one way because a channel has been machined on the housing sizer to correspond to the appropriate area on the distal aspect of the femoral notch guide. Insert the housing sizer through the femoral notch guide until it "bottoms out," verifying that the correct depth for both the conversion module and tibial eminence has been reamed (Figure 13). If the housing sizer does not bottom out, additional resection is required in the appropriate area.



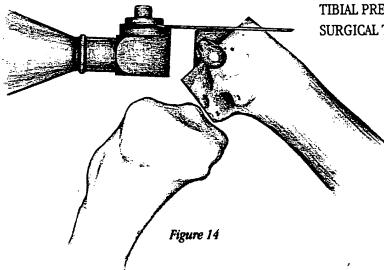
POSTERIOR-STABILIZED FEMORAL PREPARATION APPENDIX A

Chamfer Cuts

After verifying correct depth with the housing sizer, remove the femoral notch guide and attach the correct size posteriorstabilized chamfer cutting block. Center the posterior-stabilized chamfer cutting block on the two previously made distal femoral drill holes (Figure 14). The anterior and posterior femoral chamfer cuts are then performed. These cutting blocks compensate for the thickness of the conversion modules. Take care that all cuts are accurate. Since the sawblade meets the bone at an oblique angle, there is a tendency for the blade to skive away from sclerotic bone, resulting in removal of too little bone. All cuts should be carefully assessed with a straight edge.

AFTER COMPLETING THIS SECTION ON FEMORAL CUTTING FOR THE POSTERIOR-STABILIZED KNEE, RETURN TO THE TIBIAL PREPARATION SECTION OF THE SURGICAL TECHNIQUE ON PAGE 24.





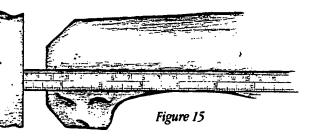
APPENDIX A POSTERIOR-STABILIZED FEMORAL PREPARATION

Measure Extension and Flexion

Assess soft tissue balance in both flexion and extension. Place the leg in full extension, but not hyperextension, and manually distract the tibia from the femur. Using a ruler, measure the medial and lateral soft tissue spaces between the ends of the bone (Figure 15). These spaces should be within one to two millimeters of being identical. Consequently, the cut surface of the femur and the tibia should be parallel. Place the knee in 90° of flexion and distract the femur. Measure the tibial and femoral spaces (Figure 16). (An

alternative method is to use the spacer block to assess the flexion and extension spaces.) Again, the gap should be of similar size on the medial and lateral

side.



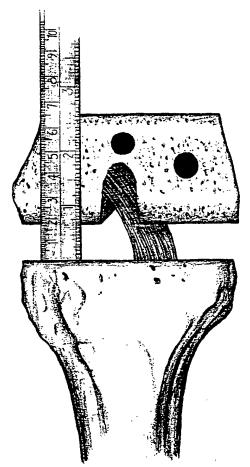
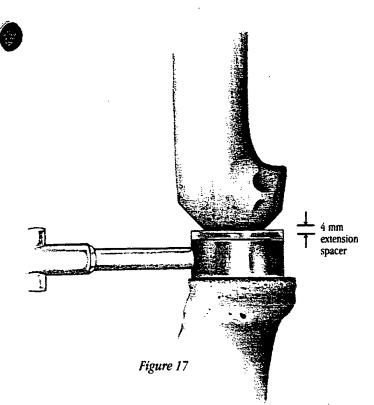


Figure 16

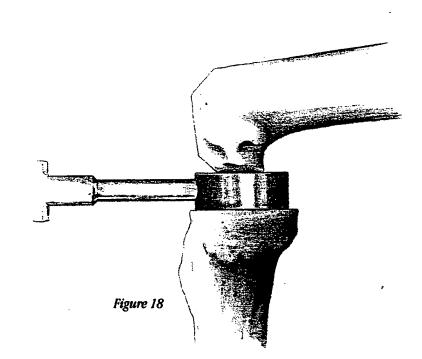
POSTERIOR-STABILIZED FEMORAL PREPARATION APPENDIX A



For the posterior-stabilized component, the extension block will be 4 mm thicker than the flexion block to compensate for the conversion module. You must add a 4 mm adaptor to the spacer block when assessing soft tissue tension in full extension (Figure 17). Assess the tautness of the collateral ligaments and correct limb alignment in both flexion and extension (Figure 18). Overtightening of the collateral ligaments, particularly in extension, will result in a flexion contracture postoperatively. Therefore, there should be physiologic give (≤2 mm) of each ligament with the spacer block in place.



Spacer Block 11-4971 through 11-4975



LIGAMENT BALANCING TECHNIQUE APPENDIXB

LIGAMENT BALANCING SURGICAL TECHNIQUE

As Described by Richard S. Laskin, M.D.

After making the distal femoral cut, fully extend the knee and place a laminar spreader medially and laterally. Expand

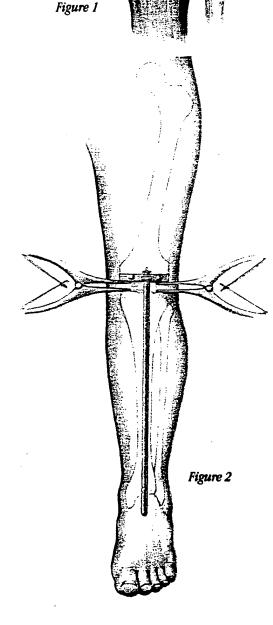
the spreaders until they are snug (Figure 1). If the distal femoral cutting block has been removed previously, replace it into position over the drill bits. Place

the extramedullary alignment rod into the tower and place the tower into the distal femoral cutting block. If the medial and lateral soft tissues are balanced properly, the end of the rod should lie over the center of the tibial plafond, slightly medial to the midpoint between the medial and lateral malleoli (Figure 2).

If the rod lies lateral to this point, it will be necessary to perform a medial release procedure. Elevate any remaining soft tissues from the tibial metaphysis to beyond the mid-coronal line.

If necessary, elevate a medial soft tissue flap including the deep capsular ligament, the pes anserinus tendons, and the superficial tibial collateral ligament. If this is not sufficient, transect the flap distally and allow it to recess proximally.

Extramedullary Alignment Rod 11-4861

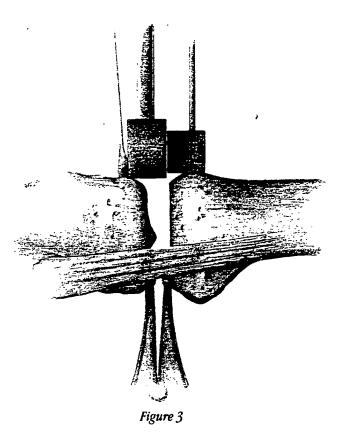


APPENDIX B

LIGAMENT BALANCING TECHNIQUE

If the rod lies medial to the tibial plafond, it will be necessary to perform a lateral release procedure. Elevate any remaining soft tissues from the lateral tibial metaphysis, including the insertion of the iliotibial band off the tubercle of Gerde. If necessary, transect the iliotibial band from inside the joint at the level of the joint line. For more severe contractures, it may be necessary to tenotomize the lateral collateral ligament and popliteus tendon as well.

Replace the laminar spreaders, if necessary, and ensure that the knee is fully extended and aligned properly. If the knee is not fully tensed, the subsequent reference line will be too low and too much bone will eventually be resected from the tibia. Likewise, if the knee is placed in recurvatum, the resection line will be too high and an insufficient amount of bone will be removed. Place the 10 mm spacer block against the inferior surface of the femoral cutting block (Figure 3). Mark the inferior surface on the block on the anterior tibia with methylene blue. At this point complete the femoral cuts beginning with femoral component sizing on page 21.



SOLUTIONS TO STABILITY PROBLEMS APPENDIX C

SOLUTIONS TO VARIOUS STABILITY PROBLEMS

There are four potential stability situations that may arise due to a variety of reasons. A trial reduction of the implants should be performed to assess soft tissue balancing, patellar tracking, and range of motion. Test the knee for anterior-posterior stability at 90° of flexion and proper tracking and stability to varus-valgus stresses throughout a range of motion. Do not check for knee stability only with the knee fully extended. In full extension, the posterior capsule is under tension and may falsely stabilize the knee. Once these tests are performed, any of the four possible stability situations may exist:

- 1. The knee is stable to A-P stress at 90° (no subluxation) and to varus-valgus stress at 0-5° (no gapping). This is the usual situation and, in such cases, no further soft tissue balancing is required.
- 2. The knee is unstable to A-P stresses at 90° (subluxation) and to varus-valgus stresses at 0-5° (gapping). This may occur if too much bone was removed from the proximal tibia. In this situation, use the next thickest tibial insert and retest. Continue testing with progressively thicker tibial inserts until stability is achieved.
- 3. The knee subluxates to A-P stresses at 90°, but appears stable to varus-valgus stresses at 0-5°. This situation may occur if there was a preexisting marked flexion contracture or varus-valgus

contracture that required surgical release. Using the spacer blocks, determine the size of the extension space. The extension space in this situation usually must be enlarged or more of the distal femur removed. Insert two 1/8" pins into the respective holes in the anterior femur. Slide the distal femoral cutting block over the pins at the 2 mm level of holes. Resect the distal femur. Redrill the femoral lug holes. Repeat the anterior and posterior chamfer cuts. Retest for A-P and varus-valgus stability by means of trial implants of appropriate sizes.

DO NOT ENLARGE THE EXTENSION SPACE BY REMOVING MORE TIBIA BECAUSE THIS WILL CHANGE THE SIZE OF THE FLEXION SPACE AS WELL.

Next, insert a thicker tibial articular trial insert and reinsert the femoral trial. Retest the knee for stability. Continue testing with progressively thicker trial inserts until stability is achieved.

Check for correct tracking of the femoral, tibial, and patellar components.

4. If the knee is tight in both flexion and extension, an additional 2 mm of bone will have to be removed from the tibia. Reinsert the pins into the tibial drill holes and replace the tibial resection guide. Adjust the guide to remove the additional 2 mm of bone and recut the proximal tibia. Repeat the trial reduction.

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IMPORTANT MEDICAL INFORMATION

Warnings and Precautions GENESIS TOTAL KNEE SYTEM For Cemented Use Only

MATERIALS

GENESIS femoral components and femoral conversion modules are Cobalt Chromium Alloy (ASTM F 75). GENESIS tibial component bases, tibial and femoral wedges, tibial pegs, and porous patellar bases are titanium 6AI-4V alloy. GENESIS tibial component articular inserts, patellar components, and Flex-Lok pegs are ultra-high molecular weight polyethylene (ASTM F 648). Porous tibial and patellar components feature a coating of unalloyed titanium (ASTM F 67) beads. The GENESIS Total Knee System is designed as a system and DOES NOT ALLOW THE SUBSTITUTION OF COMPONENTS FROM OTHER SYSTEMS.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

The general principles of good patient selection and sound surgical judgment apply to the total knee procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft tissue condition, and component placement are critical to minimize a variety of postoperative complications.

Indications:

- 1. Rheumatoid arthritis.
- Posttraumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result
- Failed osteotomies or unicompartmental replacement.

Contraindications:

- Inadequate bony support or cement support.
- 2. Previous intra-articular infections.
- Mental or neurologic conditions that tend to preempt the patient's ability or willingness to restrict activities.
- 4. Neuropathic (Charcot) joint.
- Conditions that tend to place increased loads on implants such as age, weight, and activity level, which are incompatible with a satisfactory long-term result.

Possible Adverse Effects:

- Loosening, bending, cracking, or fracture of femoral, tibial, or patellar components.
- Dislocation, subluxation, rotation phenomenon, flexion contracture, decreased range of motion, lengthening or shortening of the leg, looseness of components, or extraneous, bone or ligament laxity.
- 3. Tibial, femoral, or patellar fractures.
- Acute post-surgical wound infection, late deep wound sepsis, and/or low-grade synovitis.
- 5. Neuropathies.
- Cardiovascular disorders: wound hematoma, thromboembolic diseases including venous thrombosis and pulmonary embolus.
- Tissue reactions: Macrophage and foreign body reaction. Also, myositis ossificans.
- 8. Skin sloughs or delayed wound healing.

WARNINGS AND PRECAUTIONS

Preoperative:

- Use care in handling and storing of implant components. Cutting, bending, or scratching the surfaces of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component.
- 2. Adequate inventory of implant sizes should be available at the time of surgery.

Operative:

- Adequate and continuous support of components by cement and/or bone, and proper component size are important.
- 2. Proper axial and rotational alignment is important.
- During curing of cement, care should be taken to prevent moving of the implant components.
- Prior to closure, the surgical site should be thoroughly cleaned of bone chips, extraneous cement, ectopic bone, etc. Foreign particles at the metal-plastic interface may cause excessive wear and/or friction.

Postoperative:

- Postoperative patient care and directions and wamings to patients by physicians are extremely important. Protected weight bearing with external support is recommended for a period of time to allow healing.
- 2. Use extreme care in patient handling.
- Postoperative therapy should be structured to prevent excessive loading of the operative knee and to encourage bone healing.
- Patients should be cautioned to limit their activities as directed by their surgeon.

Packaging and Labeling:

GENESIS implants are sterilized products and should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION

All metal components have been sterilized by a minimum of 2.5 megarads of gamma irradiation. Plastic components have been sterilized by ethylene oxide gas. All components are supplied in protective trays. Inspect packages for punctures or other damage prior to surgery.

RESTERILIZATION

Metal Components

Metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all the original packaging and labeling. Protect prosthesis, particularly mating surfaces, from contact with metal or other hard objects.

Plastic Components

Plastic components may be resterilized by ethylene oxide gas, using the sterilizer manufacturer's instructions. Suggested aeration time is 48 hours at room temperature or eight hours at 60°C to 12 hours at 50°C with power aeration. Consult aerator manufacturer for more specific instructions.

INFORMATION

For further information, please contact Customer Service at 1-800-238-7538.

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